

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

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C. A. No. 06-222 (JJF)

**PLAINTIFF WYETH'S REPLY TO COUNTERCLAIMS
OF DEFENDANT IMPAX LABORATORIES, INC.**

Plaintiff Wyeth for its Reply to the Counterclaims of Defendant Impax Laboratories, Inc. ("Impax"), filed on April 25, 2006 (D.I. 7), hereby states as follows:

1. Responding to paragraph 48 of Impax's Counterclaims, Wyeth reasserts and realleges paragraphs 1-43 of its Complaint (D.I. 1), and denies the allegations of paragraphs 44-46 of Impax's Answer and Counterclaims. Wyeth has already moved to strike the allegations contained in paragraph 47 and, therefore, does not need to otherwise respond to those allegations at the present time.

2. Responding to paragraph 49 of Impax's Counterclaims, Wyeth admits, on information and belief, that Impax is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544 and another place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124. Wyeth lacks knowledge sufficient to form a belief as to the truth of the remaining allegations of paragraph 49 and, on that basis, denies the same.

3. Responding to paragraph 50 of Impax's Counterclaims, Wyeth denies that "Wyeth, Inc." is its name. Wyeth admits that it is a corporation incorporated under the laws of

the State of Delaware, with its principal place of business in Madison, New Jersey. Wyeth denies the remaining allegations of paragraph 50.

4. Responding to paragraph 51 of Impax's Counterclaims, Wyeth admits that this Court has subject matter jurisdiction over the counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), but denies that Impax is entitled to any of the relief it seeks.

5. Responding to paragraph 52 of Impax's Counterclaims, Wyeth admits that it has sued Impax for patent infringement in this Judicial District and that this Court has personal jurisdiction over Wyeth for purposes of the present litigation. In addition, Wyeth admits that venue is proper in this Court for purposes of the present litigation. Wyeth denies the remaining allegations of paragraph 52.

6. Responding to paragraph 53 of Impax's Counterclaims, Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 53 and, on that basis, denies the same.

7. Responding to paragraph 54 of Impax's Counterclaims, Wyeth admits that it is an innovative, research-based, pharmaceutical company with a long history of pioneering developments in pharmaceuticals and biotechnology that have improved the lives of millions of people around the world. Wyeth admits that in 2005 it had over \$18 billion dollars in revenue and over \$3 billion dollars in net income.

Wyeth also admits that after undergoing a lengthy, costly, and uncertain research and development process to obtain FDA approval, Wyeth began selling an immediate release dosage form of venlafaxine hydrochloride under the brand name Effexor® in 1994 in the United States. Wyeth, however, recognized the shortcomings of immediate release Effexor® early on, and began working towards possible solutions to those shortcomings with the development of an

extended release product even before the immediate release Effexor[®] product was ever approved or sold.

After undergoing yet another lengthy, costly, and uncertain research and development process to obtain FDA approval for the extended release dosage form of venlafaxine hydrochloride that it developed, Wyeth began selling an extended release dosage form of venlafaxine hydrochloride under the brand name Effexor[®] XR in 1997 in the United States. Wyeth further admits that it still sells immediate release venlafaxine hydrochloride under the brand name Effexor[®] for the treatment of depression in the United States, but states that the sales of Effexor[®] are but a small fraction of the sales of Effexor[®] XR. Wyeth denies the remaining allegations of paragraph 54.

8. Responding to paragraph 55 of Impax's Counterclaims, Wyeth admits that it owns U.S. Patent No. 4,535,186 ("the '186 patent"), which includes claims directed to the compound venlafaxine hydrochloride. Wyeth further admits that the United States Patent and Trademark Office extended the expiration date of the '186 patent from December 13, 2002 to December 13, 2007 pursuant to 35 U.S.C. § 156. In further recognition of Wyeth's additional pediatric clinical research, the FDA has extended the patent exclusivity period for the '186 patent to June 13, 2008. Wyeth denies the remaining allegations of paragraph 55.

9. Responding to paragraph 56 of Impax's Counterclaims, Wyeth admits that United States Patent Nos. 6,274,171 B1, 6,403,120 B1, and 6,419,958 B2 ("the patents-in-suit") were issued by the United States Patent and Trademark Office. Wyeth further admits that each of the patents-in-suit claim priority to the same provisional patent application, filed on March 25, 1996. Wyeth denies the remaining allegations of paragraph 56.

10. Responding to paragraph 57 of Impax's Counterclaims, Wyeth admits that Wyeth obtained FDA approval for the extended release venlafaxine hydrochloride product Effexor[®] XR. While U.S. sales of Effexor[®] plateaued at about \$225 million per year, U.S. sales of Effexor[®] XR have steadily increased to over \$2 billion per year. The benefits of Effexor[®] XR as compared to Effexor[®] are reflected in the significant differences in market performance for those products and explain the commercial success of Effexor[®] XR. Wyeth denies the remaining allegations of paragraph 57.

11. Responding to paragraph 58 of Impax's Counterclaims, Wyeth admits that Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with the FDA to obtain approval to manufacture, use and sell an extended release venlafaxine hydrochloride dosage form. Wyeth denies that Teva's certification letter to Wyeth stated that the '171, '120 and '958 patents' method claims would not be infringed by Teva. In fact, Teva's certification letter to Wyeth did not dispute Teva's infringement of the method claims of the patents-in-suit. Wyeth further admits that Wyeth sued Teva for patent infringement in the United States District Court, District of New Jersey. Wyeth also admits that a Markman hearing was held in that litigation after extensive discovery and that the Court issued a Markman Order which was later vacated. A copy of the Court's Order vacating its own Markman Order is attached as Exhibit A. Wyeth admits that the litigation with Teva was settled and that certain terms of the settlement remain confidential. However, Wyeth states that the settlement agreement was provided to the judge in the New Jersey litigation with Teva as well as to the FTC. Wyeth denies the remaining allegations of paragraph 58.

12. Responding to paragraph 59 of Impax's Counterclaims, Wyeth lacks knowledge or information sufficient to form a belief as to the truth of whether Impax's

venlafaxine extended release formulation contains microcrystalline cellulose and, on that basis, denies that allegation. Wyeth denies the remaining allegations of paragraph 59.

13. Responding to paragraph 60 of Impax's Counterclaims, Wyeth admits that an actual controversy exists between Wyeth and Impax with respect to infringement and validity of the patents-in-suit and that Wyeth states that those patents are both valid and infringed by Impax. Wyeth has already moved to strike Impax's allegations regarding the enforceability of the patents-in-suit and, therefore, need not otherwise address those allegations at the present time. Wyeth denies that Impax is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 60.

14. Wyeth admits the allegations of paragraph 61 of Impax's Counterclaims.

15. Wyeth denies the allegations of paragraph 62 of Impax's Counterclaims.

16. Wyeth denies the allegations of paragraph 63 of Impax's Counterclaims.

17. Wyeth denies the allegations of paragraph 64 of Impax's Counterclaims.

18. Wyeth denies the allegations of paragraph 65 of Impax's Counterclaims.

19. Wyeth denies the allegations of paragraph 66 of Impax's Counterclaims.

20. Responding to paragraph 67 of Impax's Counterclaims, Wyeth denies that Impax is entitled to a declaratory judgment that the '171 patent is invalid. Wyeth has already moved to strike Impax's allegations regarding the enforceability of the '171 patent and, therefore, need not otherwise address those allegations at the present time. Wyeth denies that Impax is entitled to any of the relief it seeks and denies the remaining allegations of paragraph 67.

21. Responding to paragraph 68 of Impax's Counterclaims, Wyeth denies that Impax is entitled to a declaratory judgment that the '120 patent is invalid. Wyeth has already

moved to strike Impax's allegations regarding the enforceability of the '120 patent and, therefore, need not otherwise address those allegations at the present time. Wyeth denies that Impax is entitled to any of the relief it seeks and further denies the remaining allegations of paragraph 68.

22. Responding to paragraph 69 of Impax's Counterclaims, Wyeth denies that Impax is entitled to a declaratory judgment that the '958 patent is invalid. Wyeth has already moved to strike Impax's allegations regarding the enforceability of the '958 patent and, therefore, need not otherwise address those allegations at the present time. Wyeth denies that Impax is entitled to any of the relief it seeks and further denies the remaining allegations of paragraph 69.

PRAYER FOR RELIEF

WHEREFORE, Wyeth respectfully requests that this Court enter judgment against Impax and that the Court enter an Order:

- (1) dismissing Impax's Counterclaims with prejudice;
- (2) granting Wyeth the relief it requests in its Complaint;
- (3) awarding Wyeth its attorneys' fees and costs; and
- (4) awarding Wyeth such further relief as this Court deems just and proper

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Loudon

Jack B. Blumenfeld (#1014)
Karen Jacobs Loudon (#2881)
klouden@mnat.com
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for plaintiff and counterdefendant Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

May 12, 2006
520373

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on May 15, 2006 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on May 12, 2006 upon the following in the manner indicated:

BY HAND

Mary B. Matterer
Morris, James, Hitchens & Williams
222 Delaware Avenue
P.O. Box 2306
Wilmington, DE 19899

BY FEDERAL EXPRESS

M. Patricia Thayer
John M. Benassi
Jessica R. Wolf
Heller Ehrman LLP
4350 La Jolla Village Dr.
San Diego, CA 92102

/s/ Karen Jacobs Loudon
klouden@mnat.com

EXHIBIT

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES LTD.,

Defendants.

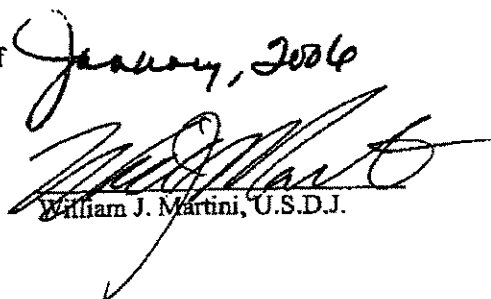
Civil Action No.: 03-1293 (WJM)

ORDER VACATING MARKMAN RULINGS

Having considered the parties Joint Motion to Vacate Markman Rulings, and as a result of the parties' having executed the Settlement and Release Agreement dated November 2, 2005, the Court hereby Orders that:

The September 6, 2005 Markman Opinion and Order, and the October 6, 2005, Letter Opinion and Order denying Wyeth's Request for Reconsideration of the Markman Opinion and Order, are hereby vacated.

SO ORDERED THIS 12th day of January, 2006


William J. Martini, U.S.D.J.